

REMARKS/ARGUMENTS

By the foregoing amendment, previously pending claims 1-35 have been cancelled, without prejudice, and new claims 36-76 have been presented. No new matter has been added. Reconsideration is respectfully requested.

New claims 36-76 are directed to previously-searched subject matter and have been drafted to overcome all objections and grounds for rejection stated under 35 U.S.C. §101 and §112 stated in the office action. Additionally, new claims 36-76 are distinguishable over the prior art cited in the Office Action for at least the reasons stated below and possibly other reasons not specifically articulated here.

New Claims 36-44:

New independent claim 36 is directed to a system for performing an arthroplasty of a hip joint in a subject having one or more known body characteristics comprising at least body weight. The system recited in claim 36 includes (A) a reamer having a part spherical head and abrading elements for reaming a socket into an acetabulum of the hip joint until cancellous bone is exposed and (B) a plurality of prosthetic femoral heads having different radii of curvature that correspond to different predetermined body characteristics including at least body weight such that, when a prosthetic femoral head that corresponds to one or more predetermined body characteristics of a subject is selected and surgically implanted in that subject's body such that it is received within an acetabular socket created by the reamer, a space will exist between the prosthetic femoral head and an inner surface of the acetabular socket and fluid having a hydrostatic pressure in the range of 0.01-5Mpa will accumulate in said space, thereby stimulating the formation of new cartilage between the prosthetic femoral head and the inner surface of the acetabular socket. A non-limiting example of this claimed system is shown in Figures 1-3 and described in the portions of the specification corresponding to Figures 1-3. None of the prior art cited in the office action describes or renders obvious the system recited in new independent claim 36.

United States Patent No. 2,785,673 (Anderson) describes a reamer that is useable to create a reamed acetabular socket and a femoral prosthesis having a head that may be received within either a natural socket, a natural socket that has been reamed or cut to a desired size or an

artificial socket created in a pelvic bone (col. 9, lines 60-63). Anderson does not describe or suggest any system wherein a prosthetic femoral head having a particular radius of curvature is selectable from other prosthetic femoral heads on the basis of a predetermined body characteristic (e.g., body weight) so that, when that femoral head is implanted, fluid having a hydrostatic pressure in the range of 0.01-5Mpa will accumulate in a space between the prosthetic femoral head and the inner surface of the acetabular socket, thereby resulting in formation of new cartilage. In the Office Action, the Examiner contends that Anderson discloses a prosthetic femoral head for hemiarthroplasty that is sized and shaped appropriately with reference to the weight of the patient (Col. 5, lines 15-20) and that this would implicitly include a radius of curvature. In response, Applicant respectfully points out that Anderson's Col. 5, lines 15-20 describes the embodiment shown in Figure 1 in which the femoral head (39) is sized to match the socket (40) and merely states that "if the socket is to be used without change" (i.e., without reaming) it is practical to provide different sized femoral heads to match variations in the acetabulum size of particular patients. (Col. 5, lines 17-23) This cited portion of Anderson does not describe any selection of a particular femoral head based on body weight. Nor does it suggest selection of a particular femoral head so that, when implanted within a reamed acetabular socket, fluid having a hydrostatic pressure in the range of 0.01-5Mpa will accumulate in a space between the prosthetic femoral head and an inner surface of the reamed acetabular socket, thereby stimulating the formation of new cartilage, as recited in claim 36.

United States Patent No. 6,660,040 (Chan et al.) describes prosthetic joints that have intentional interruptions in an articulating face of the prosthesis to provide optimal contact area or bearing surface area. Chan et al. fails to describe or suggest any system that has a plurality of prosthetic femoral heads having different radii of curvature that correspond to different predetermined body characteristics (e.g., body weight of the subject). Nor does Anderson describe or suggest any system wherein a prosthetic femoral head having a particular radius of curvature is selected and surgically implanted in that subject's body such that fluid having a hydrostatic pressure in the range of 0.01-5Mpa will accumulate in a space between the prosthetic femoral head and the inner surface of the acetabular socket to stimulating the formation of new cartilage.

PCT International Publication WO2002/50242 (Brown) describes a method for growing tissue in vitro comprising the steps of: (i) providing a deformable substrate which is seeded with

tissue-forming cells and which defines at least one flow channel containing a fluid culture medium; (ii) applying, substantially parallel to the flow channel, a cyclically varying load to the substrate, which load deforms the substrate to provide mechanical cueing for the cells; and (iii) inhibiting the flow of culture medium in one direction of the flow channel so that the deformation of the substrate causes a net flow of the culture medium along the flow channel in the opposing direction, thereby refreshing the culture medium in the flow channel. Brown does not describe any system for arthroplasty of a hip joint and does not teach or suggest the elements recited in independent claim 36.

Rushfeld et al. describe variations in cartilage thickness and geometry relative to pressure distribution in the human hip. Rushfeld et al. do not describe any system for arthroscopy of a hip joint nor does Rushfeld et al. suggest any system wherein a prosthetic femoral head having a particular radius of curvature is selectable from other prosthetic femoral heads on the basis of a predetermined body characteristic (e.g., body weight) such that when that femoral head is implanted fluid having a hydrostatic pressure in the range of 0.01-5Mpa will accumulate in a space between the prosthetic femoral head and the inner surface of the acetabular socket, thereby resulting in formation of new cartilage as recited in new claim 36.

Ishihara et al. relates to the influence of hydrostatic pressure in intact intervertebral disks, not on reamed cancellous bone. Intervertebral discs are not formed of bone. Thus, nothing in Ishihara et al. even remotely suggests that hydrostatic pressure within a space between a prosthetic femoral head and the inner surface of the acetabular socket that has been reamed in cancellous bone would result in formation of new cartilage. Thus, Ishihara et al. adds nothing that would anticipate or render obvious the subject matter of new claim 36.

Thus, even if the teachings of Anderson, Chan et al., Brown, Rushfeld et al. and/or Ishihara et al. were combined, they would still fail to disclose or render obvious the system recited in new independent claim 36.

Dependent claims 37-44 depend directly or indirectly from independent claim 36 and are also distinguishable over Anderson, Chan et al., Brown, Rushfeld et al. and/or Ishihara et al. on at least the same grounds as independent claim 36.

New claims 45-54:

Independent claim 45 recites a method for repairing a subject's hip joint comprising the steps of (A) determining at least one body characteristic comprising at least the body weight of the subject; (B) reaming the hip joint's acetabulum until cancellous bone is exposed to create a reamed acetabular socket; (C) using the at least one body characteristic determined in Step A to select a prosthetic femoral head having a radius of curvature that corresponds to the at least one body characteristic determined in Step A such that, when the selected prosthetic femoral head is surgically implanted within the reamed acetabular socket, a space will exist between the prosthetic femoral head and an inner surface of the acetabular socket and fluid having a hydrostatic pressure in the range of 0.01-5Mpa will accumulate in said space; and (D) surgically implanting the prosthetic femoral head selected in Step C such that fluid having a hydrostatic pressure in the range of 0.01-5Mpa accumulates in said space, thereby stimulating the formation of new cartilage between the prosthetic femoral head and the inner surface of the acetabular socket.

None of the Anderson, Chan et al., Brown, Rushfeld et al. and/or Ishihara et al. describe or suggest any method wherein a prosthetic femoral head having a radius of curvature that corresponds to the at least one body characteristic is selected on the basis of that body characteristic and surgically implanted within the reamed acetabular socket such that a space exists between the prosthetic femoral head and an inner surface of the acetabular socket and fluid having a hydrostatic pressure in the range of 0.01-5Mpa accumulates in that space to stimulate the formation of new cartilage between the prosthetic femoral head and the inner surface of the acetabular socket. Thus, new independent method claim 45 is also clearly distinguishable over Anderson, Chan et al., Brown, Rushfeld et al. and/or Ishihara et al.

Dependent claims 46-54 depend directly or indirectly from independent claim 45 and are distinguishable on at least the same grounds as claim 45.

New Claims 55-65

New independent claim 55 recites a reamer device for repairing a subject's hip joint comprising a rotatable reamer head with a convex distal acetabular-reaming surface and a concave proximal femoral head-reaming surface, such reamer head being i) positionable between

the femoral head and the acetabulum of the hip joint and ii) rotatable such that the convex distal acetabular-reaming surface reams the acetabulum and the concave proximal femoral head-reaming surface reams the femoral head, thereby creating reamed, congruent acetabular and femoral head surfaces with a joint space defined therebetween. A non-limiting example of this reamer device and its method of use is shown in Figures 4A-4D and described in the corresponding description of those figures.

United States Patent No. 6,231,611 (Mosseri), which was cited in the office action, describes a modular reamer that has separate attachments for reaming the femoral head and acetabulum, respectively. In the Office Action (Pg. 12), the Examiner recognizes that Mosseri fails to describe a single reamer that has both inward and outward “cutting teeth” but contends that such would be obvious over Mosseri in view of United States Patent 5,593,451 (Averill et al.). However, Averill et al. merely describes a femoral implant and method for reaming into the femur to facilitate placement of the femoral implant. Neither Mosseri nor Averill et al. describes or suggests any rotatable reamer head with a convex distal acetabular-reaming surface and a concave proximal femoral head-reaming surface that is positionable between the femoral head and the acetabulum of the hip joint and may be rotated such that the convex distal acetabular-reaming surface reams the acetabulum and the concave proximal femoral head-reaming surface reams the femoral head, thereby creating reamed, congruent acetabular and femoral head surfaces with a joint space defined therebetween as recited in independent claim 55.

Dependent claims 56-65 depend directly or indirectly from independent claim 55 and are distinguishable over Mosseri and Averill et al. on at least the same grounds as stated above with respect to independent claim 55.

New Claims 66-76

New independent claim 66 recites a method for repairing a subject's hip joint comprising the steps of (A) positioning between the joint's acetabulum and femoral head a rotatable reamer head that has a convex distal acetabular-reaming surface and a concave proximal femoral head-reaming surface and (B) rotating the reamer head such that the convex distal acetabular-reaming surface reams the acetabulum and the concave proximal femoral head-reaming surface reams the femoral head, thereby creating congruent acetabular and femoral head surfaces with a joint space defined therebetween.

New method claim 66 is distinguishable over Mosseri and Averill et al. on at least the same grounds as stated above with respect to claims 45-54.

Dependent claims 67-76 depend directly or indirectly from independent claim 66 and are distinguishable over Mosseri and Averill et al. on at least the same grounds as independent claim 66.

Conclusion

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and issuance of a notice of allowance is earnestly solicited.

Applicant hereby petitions for a three (3) month extension pursuant to 37 C.F.R. 1.136 and the Commissioner is authorized to deduct the fee for such three month extension as well as any other fee properly deemed to be due in connection with the filing of this response from Deposit Account No. 50-0878. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, the Examiner is invited to contact Applicant's undersigned counsel.

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Respectfully submitted,

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